#### PATENT COOPERATION TREATY

REC'D 0 4 JUL 2005

rom the					WIPO			
VTERNATIONAL SEARCHING AUTHORITY								
To:				• '	PCT			
W. THAD AL ADAMS EVA				WRITTEN OPINION OF THE				
2180 TWO W	ACHOVIA CE	NTER						
CHARLOTTE	2180 TWO WACHOVIA CENTER CHARLOTTE, NC 28282				INTERNATIONAL SEARCHING AUTHORITY			
			•					
					(PCT Rule 43bis.1)			
				·	A TOTAL GOAL			
				Date of mailing 3	0 JUN 2005.			
				(day/month/year) FOR FURTHER	ACTION.			
Applicant's o	r agent's file ref	erence		FORTON	See paragraph 2 below			
2765/251PCT	r			<u> </u>	Priority date (day/month/year)			
International	application No.		International filing date	(day/month/year)				
			14 February 2005 (14.0	2.2005)	31 March 2004 (31.03.2004)			
PCT/US05/0	4454	ation (IPC)	or both national classifica	tion and IPC				
			<b>0. 20.11.</b>		·			
IPC(7): A611	F 5/00 and US C	l.: 602/8						
Applicant				•	·			
BSN MEDIC	CAL, INC.			<u> </u>				
1. This opi	inion contains in	dications re	lating to the following ite	ms:				
	Box No. I	Basis of th	e opinion					
	Box No. II	Priority			17. 17. 17.			
	Box No. III	Non-estab	lishment of opinion with	regard to novelty, inv	entive step and industrial applicability			
	Box No IV Lack of unity of invention							
					to novelty, inventive step or industrial statement			
	Box No. VI		ocuments cited					
	Box No. VII		efects in the international					
	Box No. VIII	Certain o	bservations on the interna	tional application				
2. FURT	THER ACTIO	N			ill be considered to be a written opinion of the			
Interna Autho that w	ational Prelimin rity other than t ritten opinions o	his one to b of this Intern	be the IPEA and the chos ational Scarching Author	en IPEA has notified ity will not be so cons	ill be considered to be a written opinion of the best not apply where the applicant chooses and the International Bureau under Rule 66.1 bis(b) sidered.			
IPEA of For	a written reply rm PCT/ISA/220	together, wi or before t	he expiration of 22 month	written opinion of the endments, before the as from the priority da	e IPEA, the applicant is invited to submit to the expiration of 3 months from the date of mailing tte, whichever expires later.			
For fu	urther options, so	e Form PC	[/ISA/220.	-				
	idea dataile en	notes to F	orm PCT/ISA/220.		·			
J. For II	limei detans, se		<del>-</del>					
<u></u>	Name and mailing address of the ISA/ US				ficer /			
1	Mail Stop PCT, Attn: ISA/US				is (Multiple)			
	Commissioner for	Patents		1 2000	1007			
	D O Boy 1450		50	Telephone No	o. (571)272-4395			
	Alexandria, Virgi No. (703) 305-	3230						
I Facsimile	ISA/237 (cover		0004)					

International application No.
PCT/US05/04454

ox No. I Basis of this opinion	
With regard to the language, this opinion has been established on the bawas filed, unless otherwise indicated under this item.	
This opinion has been established on the basis of a translation from which is the language of a translation furnished for the purposes	
With regard to any nucleotide and/or amino acid sequence disclosed invention, this opinion has been established on the basis of:	in the international application and necessary to the claimed
a. type of material	
a sequence listing	
table(s) related to the sequence listing	
b. format of material	
in written format	
in computer readable form	
c. time of filing/furnishing	
contained in international application as filed.	
filed together with the international application in comp	
furnished subsequently to this Authority for the purposes	s of search.
In addition, in the case that more than one version or copy of or furnished, the required statements that the information in application as filed or does not go beyond the application as filed.	the subsequent or additional copies is identical to that in the
	mod, and appropriately
4. Additional comments:	nou, as appropriately
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	iiou, as spps p
4. Additional comments:	

International application No. PCT/US05/04454

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement						
Statement     Novelty (N)	Claims 8 and 13 Claims 1-7 and 9-12	YES				
Inventive step (IS)	Claims 8 and 13 Claims 1-7 and 9-12	YES				
Industrial applicability (IA)	Claims <u>1-13</u> Claims <u>NONE</u>	YESNO				

#### 2. Citations and explanations:

Claims 1-13 lack an inventive step under PCT Article 33(3) as being obvious over U.S. Patent No. 6,488,642 ("Darcey") in view of U.S.

Patent No. 6,280,815 ("Ersfeld et al").

Regarding claims 1, 3, 5, 9 and 10, Darcey substantially discloses all the claimed features. More specifically, Darcey discloses, a medical bandaging product in roll form for being dispensed in predetermined lengths suitable for a given medical use, and comprising an elongate sleeve formed of moisture-impervious material and scalable to prevent entry of moisture, and an elongate medical bandage material substantially the same length as the sleeve and sealed therein against entry of moisture until use, the medical bandago material comprising, a substrate (16), a reactive system impregnated into or coated onto the substrate and remaining stable when maintained in substantially moisture-free conditions and hardening upon exposure to sufficient moisture to form a rigid, self support structure (col. 8, lines 21-25). Darcey also discloses padding (tubular wrapping 18 at col. 7, lines 26-33) and resealing means for resealing the sleeve against entry of moisture after a predetermined length of the bandage material has been dispensed from the sleeve for use to prevent hardening of the substrate of the bandage material remaining in the sleeve (col. 8, lines 21-25).

Darcey fails to teach that the substrate comprises a foam layer, that the foam is polymer foam and that the substrate includes a textile reinforcement layer. However, Ersfeld et al. disclose a substrate comprising a polymer foam (52) and textile reinforcement layers (54, 56). The foam is impregnated with a hardenable (setting) resin as a means by which a custom shoe insert is made.

In view of Ersfeld et al., it would have been obvious to one having ordinary skill in the art to substitute the materials of construction for substrate (16) of Darcey for the materials of construction of substrate (50) of Ersfeld et al. as an obvious alternative since it appears that both substrates perform the same function.

Regarding claim 2, note col. 8, lines 9-14.

Regarding claim 4, note the table in col. 7, which discloses the formulation of the reaction system

Regarding claim 6, note Fig. 14 and col. 5, line 60-col. 6, line 14.

Regarding claim 11, the method as claimed is inherently practiced when the modified device of Darcey (see the discussion of

Regarding claim 12, Darcey discloses a package comprising an elongate sleeve (13) ad the medical material is generally the claim 1 above). same length as the sleeve. Further, disclosed in the inherent step of positioning the bandage material within the package comprises the step of placing the bandage material within the sleeve such that the bandage material extends along the length of the sleeve in a single layer (Fig. 1).

Claims 8 and 13 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest that some of the fibers from the textile reinforcement layer penetrate into the foam layer for providing rigidity and stability.

Claims 1-13 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

International application No.

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Box No. VII	Certain	defects in	the international	application

The following defects in the form or contents of the international application have been noted:

The description is objected to as containing the following defect(s) under PCT Rule 66.2(a)(iii) in the form or contents thereof: Page 8, para. [0036], line 4, "14" should read --13--.

Form PCT/ISA/237 (Box No. VII) (January 2004)

#### PATENT COOPERATION TREATY

REC'D 0 4 JUL 2005

om the				WIPO			
TERNATIONAL SEARCHING AUTHORITY				DCT			
Io: W. THAD ADAMS III ADAMS EVANS P.A. 2180 TWO WACHOVIA CENTER CHARLOTTE, NC 28282				WF INTERNATIO	PCT RITTEN OPINION OF THE ONAL SEARCHING AUTHORITY		
					(PCT Rule 43bis.1)		
				Date of mailing ?	0 JUN 2009		
Applicant's	or agent's file re	ference		FOR FURTHER	ACTION See paragraph 2 below		
765/251PC	OT		International filing date	(day/month/year)	Priority date (day/month/year)		
nternationa	l application No.				31 March 2004 (31.03.2004)		
CT/US05/	04454	ation (IPC)	14 February 2005 (14.0 or both national classifications)	tion and IPC	St March 200 (Control		
PC(7): A6 Applicant	1F 5/00 and US C	71 002/0					
••	ICAL, INC.						
	pinion contains in	_	lating to the following ite	ms.			
$\boxtimes$	Box No. I	Basis of th	e opinion				
	Box No. II	Priority			1 descript applicability		
	Box No. III	Non-estab	lishment of opinion with	regard to novelty, inv	ventive step and industrial applicability		
	Box No. IV	Lack of u	nity of invention				
$\boxtimes$	Box No. V	Reasoned applicabil	statement under Rule 431 ity; citations and explana	bis.1(a)(i) with regard tions supporting such	I to novelty, inventive step or industrial a statement		
	Box No. VI		ocuments cited		:		
$\overline{\boxtimes}$	Box No. VII	Certain de	efects in the international	application			
	Box No. VIII	Certain o	bservations on the interna	tional application			
If a (Internal Author)	national Prelimi ority other than written opinions	national pre- nary Examinathis one to be of this Intern	the IPEA and the chosational Scarching Author	en IPEA has notified ity will not be so con			
IPEA of Fo	a written reply orm PCT/ISA/22	or before t	he expiration of 22 month	written opinion of the endments, before the is from the priority da	e IPEA, the applicant is invited to submit to the e expiration of 3 months from the date of mailing ate, whichever expires later.		
For	further options, s	ee Form PC	1/15A/220.				
3. For	further details, sc	e notes to Fo	orm PCT/ISA/220.				
Name an	d mailing address	of the ISA/	US	Authorized of	flicer Last		
Name and mailing address of the ISA/US  Mail Stop PCT, Attn: ISA/US				Kim M. Lew	is Much from		
1	Commissioner for P.O. Box 1450		•	m.1 1	(571)272-4395		
	Alexandria, Virgi	3230		Telephone No	0. (571)272-4395		
Facsimii	7/ISA/237 (cover	sheet) (Janu	ary 2004)				

Form PCT/ISA/237(Box No. I) (January 2004)

International application No.
PCT/US05/04454

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Box No. I Basis of this opin	nion					
With regard to the language, was filed, unless otherwise in						
This opinion has been which is the language			from the original l	anguage into ti search (under l	ne following la Rules 12.3 and	nguage 23.1(b)).
which is the language  With regard to any nucleotid	or a naislanon		and in the internation	nal application	and necessary	to the claimed
With regard to any nucleotid invention, this opinion has be	le and/or amino ac een established on t	the basis of:	ed in the internation			•
a. type of material						
a sequence listi	ng				•	
table(s) related	to the sequence lis	ting		,		
b. format of material						,
in written form	at					
in computer re	adable form					
c. time of filing/furnish	ning		,			
	nternational applic	ation as filed.				
		nal application in co	mputer readable fo	rm.		
		uthority for the purp				
furnished sub	sequently to this A	addonly to have part				
3. In addition, in the corfurnished, the reapplication as filed	ease that more than quired statements or does not go bey	one version or copy that the information and the application a	of a sequence list in the subsequent is filed, as appropri	ing and/or tabl or additional ate, were furni	e relating ther copies is ident shed.	eto has been fil ical to that in t
4. Additional comments:						
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### WRITTEN OPINION OF THE

Form PCT/ISA/237 (Box No. V) (January 2004)

International application No. PCT/US05/04454

WRITTEN OPINION OF INTERNATIONAL SEARCHING	101/0803/01/51		
Jan Dulo /	13 his 1(a)(i) with reg	ard to novelty, inventive step or industri	al
Box No. V Reasoned statement under Kule applicability; citations and explan	nations supporting su	ch statement	
applicability, craws			
1. Statement			YES
Novelty (N)			NO NO
140 rately (1.1)	Claims 1-7 and	<b>-12</b>	
	•		YES
Inventive step (IS)	Claims 8 and 13		NO NO
	Claims 1-7 and	9-12	
,			YES
Industrial applicability (IA)	Claims 1-13		NO
	Claims NONE		,·`
2. Citations and explanations:  Claims 1-13 lack an inventive step under PCT Artic	. aaraa - L-i ahuian	over H.S. Patent No. 6,488,642 ("Darcey") in	view of U.S.
Claims 1-13 lack an inventive step under PCT Artic	cle 33(3) as being obviou	y over our remaining	201
Patent No. 6,280,815 ("Ersield et al.).	y substantially discloses	all the claimed features. More specifically, Date	al use, and
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L C	L disciose a paesaran i i i	1 1 1 - sustain shoe insert is mai	GC.
E substrate (16) Of 1) SICCV IOI UIC III	Mitcharp or oarm manner	of substrate (50) of Ersteid et al. as an obvious a	1,01,22,1
since it appears that both substrates periorin the sa	HILO TALLE IS CO.		/
Regarding claim 2, note col. 8, intes year	7 which discloses the fo	ormulation of the reaction system	
Regarding claim 7, note dispenser (11).	t : 1the proctice	ed when the modified device of Darcey (see the	discussion of
Regarding claim 11, the method as clair	med is innerently practice	whom the terms	operally the
claim I above).	package comprising an	clongate sleeve (13) ad the medical material is g oning the bandage material within the package c	omprises the
Regarding claim 12, Darcey discloses a same length as the sleeve. Further, disclosed in it	he inherent step of position	ning the bandage material within the paskage of	e in a single
same length as the sleeve. Further, disclosed in the step of placing the bandage material within the ski	eeve such that the banda	is matchai externs mong and a second	
layer (Fig. 1).		C. L	at some of the
layer (Fig. 1).  Claims 8 and 13 meet the criteria set out in PCT.	Article 33(2)-(3), becaus	the prior art does not teach or fairly suggest up	TE SOUTH OF HIS
Claims 8 and 13 meet the criteria set out in PCT fibers from the textile reinforcement layer penetr	ate into the foam layer fo	r providing rigidity and salomes.	
Claims 1-13 meet the criteria set out in PCT Arti	cle 33(4), and thus have	industrial applicability because the subject matter	er claimed can
Claims 1-13 meet the criteria set out in PC1 Aid be made or used in industry.			
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International application No.

PCT/US05/04454

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The following defects in the form or contents of the international application have been noted:

The description is objected to as containing the following defect(s) under PCT Rule 66.2(a)(iii) in the form or contents thereof: Page 8, para. [0036], line 4, "14" should read --13--.

Form PCT/ISA/237 (Box No. VII) (January 2004)